

## **REMARKS**

The non-final Office Action mailed December 7, 2010 has been carefully reviewed and this paper is responsive thereto. Claims 1-37 are pending. Claims 1-37 stand rejected. To facilitate prosecution, claims 14 and 32 have been amended. Reconsideration of the pending claims is requested in view of the following remarks.

### **Claim Rejection Under 35 USC §112**

Claims 14 and 32 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To facilitate prosecution, claims 14 and 32 have been amended to delete certain wording from the preamble and place similar wording as a positive recitation in claims 14 and 32. In view of the foregoing, it is respectfully submitted that the rejection of claims 14 and 32 has been rendered moot.

### **Claim Rejections Under 35 USC §102**

Claims 1-7, 12-16 and 20-37 were rejected under 35 USC §102(b) as being anticipated by Shaw, U.S. Patent No. 6,014,587 ("Shaw").

Claims 18-19 were rejected under 35 USC §102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shaw.

Claims 8-11, 17, 28-31 and 33 were rejected under 35 U.S.C. 103(a) as obvious over Shaw.

It appears that the Office Action misinterprets Shaw, as discussed below.

Claim 1 recites "(a) receiving a first set of information from a user, the first set of information being associated with a first treatment therapy configuration; (b) assessing whether the first set of information is within a range of safety". In addressing claim 1, the Office Action states:

Shaw et al. discloses a method for configuring and testing therapy parameters for treatment of a nervous system disorder, by receiving a first set of information form (sic, from) the user, where in the first set of information is associated with

the therapy configurations and assessing whether the information is within a range of safety (col. 30, lines 20-25 and lines 31-34)

...

[in further describing what Shaw discloses] (b) assessing whether the first set of information is within a range of safety (col. 30, lines 20-23, the pulse width is measured and compared to the specified pulse width to assess whether it is within an acceptable tolerance or range of safety; and col. 30, lines 37-40, the current and voltage must be within a specific range of acceptable values);

The cited portion of Shaw is provided below, along with preceding paragraphs which provide context:

To test the software frequency monitor, the safety processor sets up a pulse train at a first frequency, but then assumes the frequency to be a different frequency value. The software processor then checks the frequency of each pulse by measuring the time between the corresponding edges of subsequent pulses (i.e., leading edge-to-leading edge or trailing edge-to-trailing edge. If the measured frequency falls outside of a specified range, as it should, the safety processor shuts down the pre-treatment ECT pulse train that is being delivered into the 300 ohm internal load. In this way, the safety processor can verify that its software frequency monitor is functioning properly.

The safety processor also verifies that the hardware frequency monitor is functioning properly. It accomplishes this by setting up a pulse train having a frequency in excess of the maximum allowable frequency. In the preferred embodiment, this maximum allowable frequency is approximately 220 Hz. The safety processor then configures the system to deliver this pulse train into the internal 300 ohm load and then verifies that the hardware frequency monitor disabled the delivery of the pulse train in response to this excessive frequency.

If all of these hardware self-tests are performed without error, the system enters the armed state 506. While in the armed state, the system continuously monitors patient impedance and checks to see that all patient monitoring leads are connected to the patient. If either of these two conditions are not met, the system disarms and displays an appropriate error message. (Col. 29, lines 8-36).

...

The remaining tests are performed after the treatment has begun. Moreover, several of the tests (4-8) are performed on a pulse-by-pulse basis. The pulse width is measured by software by dating the time stamps that are trapped by the system processor upon detection of the trailing and leading edges of each pulse. The pulse width is then determined by simply subtracting the time stamp of the

leading edge from that of the trailing edge. This detected pulse width is then compared with the specified pulse width, as set on the front panel, to determine whether the measured pulse width is within an acceptable tolerance of the specified pulse width. If the pulse width falls outside of that range, the safety processor terminates the treatment.

Similarly, the safety processor measures the frequency of the pulse train on a pulse-by-pulse or, rather, period-by-period basis. It does this by subtracting the time stamp of a leading edge of a pulse from a time stamp of a leading edge of the subsequent pulse to determine the period of that pulse. This detected period is then compared with the reciprocal of the specified frequency to determine whether the measured frequency is within an acceptable tolerance or range of the specified frequency. If not, the treatment is terminated.

The safety processor also monitors the voltage and current of each pulse and compares these measured values to those specified by the user. If this measured current is not within a predetermined range of the specified value, the processor terminates the treatment. The voltage on the other hand must be less than a predetermined maximum voltage. (Col. 30, lines 13-40).

It is noted that the last three paragraphs reproduced above were cited in the Office Action as accounting for assessing whether a set of information received from a user is within a range of safety (as quoted previously). Shaw's above described tests, concerning ensuring that measured pulses are actually delivered within acceptable tolerance ranges (i.e. pulse width and frequency tolerances), are hardware self-tests to see that the circuitry can perform as specified. Hardware tests to determine whether the device can actually perform within a specified parameter does not constitute "assessing whether the first set of information [received from a user] is within a range of safety". (Claim 1). In the case of Shaw, the results of the hardware tests are not information received from a user. It is respectfully submitted that at least the relied upon portions of Shaw do not disclose all elements of independent claims 1 and 25.

The pending dependent claims are patentable for at least the same reasons that independent claims 1 and 25 are patentable, and for the additional features claimed therein.

For at least the above reasons, it is respectfully submitted that the pending claims should be allowed.

## Conclusion

Applicants respectfully requests reconsideration of the pending claims and a finding of their allowability. A notice to this effect is respectfully requested. Please feel free to contact the undersigned should any questions arise with respect to this case that may be addressed by telephone.

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